

K003333

JAN - 4 2001

6-1

F. 510(k) Summary

Applicant: Stick Tech Ltd, PO Box 114, 20521 Turku, Finland
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Fax: +358-2-241 0032

Contact Person: Ilkka Kangasniemi, Ph.D.

U.S. Agent to respond to
FDA requests: William M. Troetel, Ph.D.
80 Parkway West
Mount Vernon, NY 10552
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Fax: (914) 667-3993
wtroetel@westnet.com

Date Prepared: October 19th, 2000

Device Trade Name: StickTM

Device Common Name : Glass fiber reinforcement material

Device Classification Name: Denture relining, repairing, or rebasing resin
(21 CFR §872.3760)

Description of Device:

StickTM is a pre-manufactured product made of glass fibers and highly porous polymer matrix for reinforcing dental acrylic polymers. **StickTM** is made of unidirectional fibers which increase the strength and stiffness of the final product perpendicular to the direction of the fibers.

Intended Use:

As reinforcement in manufacturing and/or repairing full or partial dentures as well as overdentures and orthodontic appliances.

As reinforcement for temporary and/or permanent plastic/composite inlays, onlays and bridges.

As reinforcement for customized splints used to immobilize teeth which may be required post-trauma, post-operative, or for orthodontic therapy.

Stick™ is substantially equivalent to Ribbond, cleared under K913040 dated October 7, 1991

Testing which has been performed on **Stick™** indicates that the devices have the same intended use but somewhat different technological characteristics.

Stick™ is a polymer pre-impregnated unidirectional continuous glass fiber whereas Ribbond is an ultra high modulus polyethylene fiber ribbon with no pre-impregnation. The different technological characteristics of **Stick™** does not raise new questions of safety and effectiveness and demonstrates that the device is as safe and effective as the predicate device.

Test results indicate that there are no hazards presented with the use of **Stick™** as compared with the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Stick Tech Limited
C/O Mr. William M. Troetel
William M. Troetel, LLC
80 Parkway West
Mount Vernon, New York 10552

Re: K003333
Trade Name: Stick
Regulatory Class: II
Product Code: EBI
Dated: October 19, 2000
Received: October 25, 2000

Dear Mr. Troetel:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic

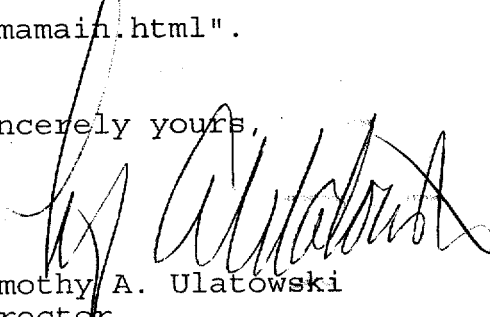
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Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

B. Indications for Use510(k) Number (if known): K003333Device Name: Stick™

Indications For Use:

- As reinforcement in manufacturing and/or repairing full or partial dentures as well as overdentures and orthodontic appliances.
- As reinforcement for temporary and/or permanent plastic/composite inlays, onlays and bridges.
- As reinforcement for customized splints used to immobilize teeth which may be required post-trauma, post-operative, or for orthodontic therapy.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-the-Counter Use

(Optional Format 1-2-96)

Susan Ruane
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K003333